DEC 14 2005

K053165

510(k) Summary – ISE Indirect Na, K, Cl for Gen.2

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

Roche Diagnostics
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3723

Contact person: Kerwin Kaufman

Date prepared: November 11, 2005

Device Name

Proprietary name: ISE Indirect Na, K, Cl for Gen.2

Common names:

Sodium Test System
Potassium Test System
Chloride Test System

Classification names:

Ion-Specific Electrode Sodium
Ion-Specific Electrode Potassium
Ion-Specific Electrode Chloride

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Device Description

An Ion-Selective Electrode (ISE) makes use of the unique properties of certain membrane materials to develop an electrical potential (electromotive force, EMF) for the measurements of ions in solution. The electrode has a selective membrane in contact with both the test solution and an internal filling solution. The internal filling solution contains the test ion at a fixed concentration. Because of the particular nature of the membrane, the test ions will closely associate with the membrane on each side. The membrane EMF is determined by the difference in concentration of the test ion in the test solution and the internal filling solution. The EMF develops according to the Nernst equation for a specific ion is solution (see package insert for further explanation).

The complete measurement system for a particular ion includes the ISE, a reference electrode and electronic circuits to measure and process the EMF to give the test ion concentration. The sodium and potassium electrodes are based on neutral carriers and the chloride electrode is based on an ion exchanger.

Intended use / Indications for use

The ISE module of the Roche / Hitachi systems is intended for the quantitative determination of sodium, potassium, and chloride in serum, plasma, or urine using ion-selective electrodes.

Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Predicate Device

We claim substantial equivalence to the predicate device, original ISE Na, K, Cl, cleared in K953239.

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510(k) Summary – ISE Indirect Na, K, Cl for Gen.2, Continued

Substantial equivalency – Similarities

The table below indicates the similarities between the modified ISE Indirect Na, K, Cl for Gen.2 device and its predicate device (original ISE Na, K, Cl, K953239).

Feature	Predicate device: original ISE Na, K, Cl (K953239)	Modified device: ISE Indirect Na, K, Cl for Gen.2
General		
Instruments	Roche Hitachi automated analyzer family	Same
Intended Use/ Indications for Use	For the quantitative determination of sodium, potassium, and chloride in serum, plasma, and urine. Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.	The ISE module of the Roche / Hitachi systems is intended for the quantitative determination of sodium, potassium, and chloride in serum, plasma, or urine using ion-selective electrodes. Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

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510(k) Summary – ISE Indirect Na, K, Cl for Gen.2, Continued

Feature	Predicate device: original ISE Na, K, Cl (K953239)	Modified device: ISE Indirect Na, K, Cl for Gen.2
Test principle		
Sample types	Serum, Plasma (Lithium heparin) or Urine	Same
Determination of Sodium, Potassium and Chloride	An Ion-Selective Electrode (ISE) makes use of the unique properties of certain membrane materials to develop an electrical potential (electromotive force, EMF) for the measurements of ions in solution. The electrode has a selective membrane in contact with both the test solution and an internal filling solution. The internal filling solution contains the test ion at a fixed concentration. Because of the particular nature of the membrane, the test ions will closely associate with the membrane on each side. The membrane EMF is determined by the difference in concentration of the test ion in the test solution and the internal filling solution. The EMF develops according to the Nernst equation for a specific ion is solution (see package insert for further explanation). The complete measurement system for a particular ion includes the ISE, a reference electrode and electronic circuits to measure and process the EMF to give the test ion concentration. The sodium and potassium electrodes are based on neutral carriers and the chloride electrode is based on an ion exchanger.	Same

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510(k) Summary – ISE Indirect Na, K, Cl for Gen.2, Continued

Feature	Predicate device: original ISE Na, K, Cl (K953239)	Modified device: ISE Indirect Na, K, Cl for Gen.2
Electrode / Reagent information		
Ion-Specific Electrodes	Sodium Electrode/ Cartridge Potassium Electrode/ Cartridge Chloride Electrode/ Cartridge Reference Electrode/ Cartridge	Same
Electrode Onboard Stability	Sodium, Potassium and Chloride Electrodes, 2 months or 9000 tests Reference Electrode, at least 6 months	Same
Calibrators S1, S2 for two-point calibration	S1: ISE Standard Low S2: ISE Standard High	Same
Auxiliary Reagents	ISE 1 N potassium chloride (Reference Electrolyte)	Same
Performance characteristics		
Reportable Range	Serum/Plasma: Na^+: 80 – 180 mmol/L K^+: 1.5 – 10 mmol/L Cl^-: 60-140 mmol/L Urine: Na^+: 10 – 250 mmol/L K^+: 1 – 100 mmol/L Cl^-: 20 – 250 mmol/L	Serum/Plasma: Na^+: Same K^+: Same Cl^-: Same Urine: Na^+: Same K^+: Same Cl^-: 10 – 250 mmol/L

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510(k) Summary – ISE Indirect Na, K, Cl for Gen.2, Continued

Substantial equivalency – Differences

The table below indicates the differences between the modified ISE Indirect Na, K, Cl for Gen.2 device and its predicate device (original ISE Na, K, Cl, K953239).

Feature	Predicate device: original ISE Na, K, Cl (K953239)	Modified device: ISE Indirect Na, K, Cl for Gen.2
Electrode / Reagent information		
ISE Diluent Composition	650 mmol/L Boric acid Preservative (Gentamicin based)	10 mmol/L HEPES buffer 7 mmol/L Triethanolamine Preservative
ISE Internal Standard Composition	650 mmol/L Boric acid 32.3 mmol/L Sodium Chloride 12.9 mmol/L Sodium bicarbonate 1.6 mmol/L Potassium phosphate Preservative (Gentamicin based)	10 mmol/L HEPES buffer 7 mmol/L Triethanolamine 3.06 mmol/L Sodium chloride 1.45 mmol/L Sodium acetate 0.16 mmol/L Potassium chloride Preservative
Electrode Slope Ranges	Sodium: 32.0 to 68.0 mV/decade Potassium: 32.0 to 68.0 mV/decade Chloride: -35.0 to -68.0 mV/decade	Sodium: 50 to 68 mV/decade Potassium: 50 to 68 mV/decade Chloride: -40 to -68 mV/decade
Calibrator, S3 for compensation	Precical Calibrator Serum	ISE Compensator (serum based)
Quality control	Precitrol-N Control Serum and Precitrol-A Control Serum or other commercially available controls	Precinorm U and Precipath U or other commercially available controls
ISE Cleaning Solution	4 N NaOH/System Cleaning Solution	ISE Cleaning Solution: Sodium hydroxide, 12% with Sodium hypochlorite solution < 2% active Cl (4 N NaOH/System Cleaning Solution can also be used)
Traceability	NIST reference material	Flame Photometry, Coulometry with NIST reference material
Reagent On board Stability	ISE 1N KCl, ISE Diluent working solution and ISE Internal Reference working solution, stable at 20-25 C until expiration date on bottle label.	ISE 1N KCl, up to the expiration date ISE Diluent and ISE Internal Reference, 6 weeks on board.

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<table>
<tr><th>Feature</th><th>Predicate device: original ISE Na, K, Cl (K953239)</th><th>Modified device: ISE Indirect Na, K, Cl for Gen.2</th></tr>
<tr><td colspan="3">Labeled performance characteristics</td></tr>
<tr><td>Precision</td><td>

Total Imprecision, Serum

Sodium (mmol/L), n=63:

Mean	151.6	128.0
Total SD	0.89	0.79
Total CV	0.6%	0.6%

Potassium (mmol/L), n=63:

Mean	6.32	3.50
Total SD	0.05	0.03
Total CV	0.8%	0.8%

Chloride (mmol/L), n=63:

Mean	120.4	98.7
Total SD	1.39	0.71
Total CV	1.2%	0.7%

Total Imprecision, Urine

Sodium (mmol/L):

N	60	63
Mean	59.4	163.3
Total SD	0.93	0.91
Total CV	1.6%	0.6%

Potassium (mmol/L):

N	60	63
Mean	23.58	52.64
Total SD	0.22	0.70
Total CV	0.9%	1.3%

Chloride (mmol/L):

N	60	63
Mean	52.7	144.7
Total SD	0.92	1.50
Total CV	1.7%	1.0%

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Between day Imprecision, Plasma

Sodium (mmol/L), n=21:

Mean	143.0	128.5
SD	0.51	0.52
CV	0.4%	0.4%

Potassium (mmol/L), n=21:

Mean	6.95	4.27
SD	0.02	0.01
CV	0.3%	0.3%

Chloride (mmol/L), n=21:

Mean	118.8	92.7
SD	0.42	0.42
CV	0.4%	0.5%

Between day Imprecision, Urine

Sodium (mmol/L), n=21:

Mean	23.7	160.5
SD	0.77	0.64
CV	3.3%	0.4%

Potassium (mmol/L), n=21:

Mean	19.86	59.67
SD	0.15	0.68
CV	0.8%	1.1%

Chloride (mmol/L), n=21:

Mean	21.4	154.5
SD	0.51	1.00
CV	2.4%	0.6%

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510(k) Summary – ISE Indirect Na, K, Cl for Gen.2, Continued

Feature	Predicate device: original ISE Na, K, Cl (K953239)	Modified device: ISE Indirect Na, K, Cl for Gen.2
Labeled performance characteristics		
Linearity	Sodium (serum): 59.8–199.6 mmol/L with deviation of less than 2.0 mmol/L or 3% Potassium (serum): 0.52-12..20 mmol/L with deviation of less than 0.1 mmol/L or 1% Chloride (serum): 43.4-164.5 mmol/L with deviation of less than 0.4 mmol/L or 1%	Sodium: Serum = 80-180 mmol/L Urine = 10-250 mmol/L Deviation ± 5% from 40.0-250 mmol/L or ± 3 mmol/L at concentrations < 40.0 mmol/L Potassium: Serum = 1.5-10 mmol/L Urine = 10-100 mmol/L Deviation ± 10 % from 10.0-100.0 mmol/L, ± 5% from 1.0-10.0 mmol/L Chloride: Serum = 60.0-140.0 mmol/L Urine = 10.0 to 250.0 mmol/L Deviation ± 5 % from 45.0-250.0 mmol/L, ± 8 mmol/L from < 45.0 mmol/L

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Feature	Predicate device: original ISE Na, K, Cl (K953239)	Modified device: ISE Indirect Na, K, Cl for Gen.2
Labeled performance characteristics		
Method Comparison	Sodium (serum), Passing-Bablok: x method = Hitachi 717 y method = Hitachi 917 n = 99 y= 1.013x – 2.21, r = 0.998 Potassium (serum), Passing-Bablok: x method = Hitachi 717 y method = Hitachi 917 n = 94 y= 0.980x + 0.087, r = 1.000 Chloride (serum), Passing-Bablok: x method = Hitachi 717 y method = Hitachi 917 n = 99 y= 1.004x + 0.65, r = 0.997	Sodium (plasma), Passing-Bablok: x method = Hitachi 911 (predicate reagent) y method = Hitachi 917 (modified reagent) n = 58 y= 1.000x – 1.300, r = 0.988 Potassium (plasma), Passing-Bablok: x method = Hitachi 911 (predicate reagent) y method = Hitachi 917 (modified reagent) n = 58 y= 1.000x - 0.070, r = 0.999 Chloride (plasma), Passing-Bablok: x method = Hitachi 911 (predicate reagent) y method = Hitachi 917 (modified reagent) n = 58 y= 0.993x - 0.664, r = 0.994
Endogenous interferences	Reference Literature	Hemolysis: *Sodium and Chloride*, no significant interference up to 1000 mg/dL hemoglobin *Potassium*, hemoglobin >100 mg/dL increase apparent potassium levels significantly Icterus: No significant interference from conjugated and unconjugated bilirubin up to 60 mg/dL Lipemia: No significant interference up to 2000 mg/dL Intralipid.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 14 2005

Mr. Kerwin Kaufman, MBA, MT (ASCP)
Regulatory Affairs Consultant
Centralized Diagnostics
Roche Diagnostics
9115 Hague Road
P.O. Box 50416
Indianapolis, IN 46250

Re: k053165
Trade/Device Name: ISE Indirect Na, K, CI for Gen.2
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium test system
Regulatory Class: Class II
Product Code: JGS, CEM, CGZ
Dated: November 11, 2005
Received: November 14, 2005

Dear Mr. Kaufman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **ISE Indirect Na, K, Cl for Gen.2**

Indications For Use:

The ISE module of the Roche / Hitachi systems is intended for the quantitative determination of sodium, potassium, and chloride in serum, plasma, or urine using ion-selective electrodes.

Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Prescription Use **XXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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